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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 667,569	09 21 2000	R. Rogers Yocum	BGI-141CP	8755

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LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12 03 2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/667,569

Applicant(s)

YOCUM ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 7, 12, 14-53, 62, 67-75, 82, 88, 90, 97-99, 102, 104, 106 and 108-110 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

U.S. Patent and Trademark Office  
PTO-326 (Rev. 04-01)

**Office Action Summary**

Part of Paper No. 7

Continuation of Disposition of Claims: Claims pending in the application are 1,2,7,12,14-53,62,67-75,82,83,88,90,97-99,102,104,106 and 108-110.

## DETAILED ACTION

### *Application Status*

1. A preliminary amendment was submitted on September 21, 2000 amending the claims. Claims 1, 2, 7, 12, 14-53, 62, 67-75, 82, 83, 88, 90, 97-99, 102, 104, 106, and 108-110 are pending in the instant application. The Examiner notes that Claim 98 was inadvertently omitted in the cancellation of claims; Claim 98 depends from cancelled Claims 86 and 93. Applicants are advised to cancel said claim; Claim 98 is not included in the restriction requirement below.

### *Restriction*

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 1, 2, 7, 12, 14-34, 36, 37, 39-44, 46-50, 51 drawn to methods of making panto-compounds in microorganisms *in vivo*, classified in class 435, subclass 128.
  - II. Claims 35, 38 drawn to methods of producing panto-compounds *in vitro* using *Bacillus* enzymes, classified in class 435, subclass 128.
  - III. Claims 52 and 53 drawn to methods for identifying modulators of pantothenate kinase, classified in class 435, subclass 15.
  - IV. Claims 62 and 67-75, 82, 83, 88, 90, 97, 99, 108, 109 drawn to microorganisms overexpressing at least one *Bacillus* pantothenate biosynthetic enzyme, vectors and nucleic acid sequences thereof; microorganisms having a mutant *coaX* gene, vectors and nucleic acid sequences thereof; microorganisms containing a *coaX* gene, vectors and nucleic acid sequences thereof; microorganisms that overproduce panto-compounds by virtue of a deregulated pantothenate pathway and a mutation in CoA biosynthesis, classified in class 435, subclass 252.3.

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- V. Claims 102, 104, 106, and 110 drawn to pantothenate biosynthetic enzymes, classified in class 435, subclass 183.

3. The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I and II, while both being methods of producing panto-compounds, are distinct methods due to their different reagents, particularly, the methods of Group I use microorganisms to produce the panto-compounds while the methods of Group II use the isolated pantothenate biosynthetic enzymes to produce these same compounds. Moreover, these methods use distinct method steps. Thus, Groups I and II are patentably distinct. While these Groups are classified identically, their search would not be co-extensive based on the different reagents and method steps as noted above.

The methods of Groups I and II are each distinct from the methods of Group III because the methods use wholly different methods steps and reagents to produce wholly different products. Thus, Groups I and II are patentably distinct from Group III. Moreover, their search would be burdensome based in their distinct class, subclass classification.

The methods of Groups I and II and III are related to the products of Groups IV and V as methods of using and products used. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products can be used for materially different processes of using the product, such as in recombinant production of the enzymes for use in production of antibodies. Thus, Groups I and

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II and III are patentably distinct from Groups IV and V. Moreover, their search would be burdensome based in their distinct class, subclass classification.

The DNA of Group IV is related to the enzymes of Group V by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups IV and V are patentably distinct. Moreover, their search would be burdensome based in their distinct class, subclass classification.

### *Election of Species*

4. This application contains claims directed to the following patentably distinct species of the claimed inventions; Groups I, II, IV, and V require species elections as denoted below. If any of Groups I, II, IV, or V are elected, Applicant is further required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

For Group I, Claims 1, 2, 16\*, 18\*, 19, 24, 28, 48\*, and 51 are generic. The "\*" indicates generic *in vivo* genes.

Species of Group I:

- a) overexpressing ketopantoate hydroxymethyltransferase (*panB*)  
Claims 26, 27, 33, 34, 51
- b) overexpressing pantothenate synthetase (*panC*)  
Claims 26, 27, 33, 34, 51
- c) overexpressing aspartate- $\alpha$ -decarboxylase (*panD*)  
Claims 14, 15, 17, 23, 26, 27, 32, 33, 34, 36, 37, 49, 51
- d) overexpressing ketopantoate reductase (*panE*)  
Claims 7, 12, 26, 27, 33, 34, 49, 51

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- e) overexpressing acetohydroxyacid synthetase (*ilvBN*)  
Claims 16, 18, 20, 29, 48, 51
- f) overexpressing acetolactate synthase (*alsS*)  
Claims 20, 29, 51
- g) overexpressing acetohydroxyacid isomeroreductase (*ilvC*)  
Claims 16, 18, 21, 30, 48, 51
- h) overexpressing dihydroxyacid dehydratase (*ilvD*)  
Claims 16, 18, 22, 31, 48, 51
- i) expressing a mutant valine-pyruvate amino acid transferase (*avtA*)  
Claims 25, 50, 51
- j) expressing a mutant branched-chain amino acid transferase (*ilvE*)  
Claims 16, 18, 25, 48, 50, 51
- k) expressing a mutant asparaginase (*ansB*)  
Claims 25, 50, 51
- l) expressing a mutant acetolactate decarboxylase (*alsD*)  
Claims 25, 50, 51
- m) having a mutant pantothenate kinase (*coaX*)  
Claims 39-47, 48-50
- n) having a mutant pantothenate kinase (*coaA*)  
Claims 40-47, 48-50

For Group II, Claim 35 is generic.

Species of Group II:

- a) using ketopantoate hydroxymethyltransferase (*panB*)
- b) using pantothenate synthetase (*panC*)
- c) using aspartate-a-decarboxylase (*panD*)  
Claim 38
- d) using ketopantoate reductase (*panE*)

For Group IV, Claims 62, 71, 82, 83, 97, 99 are generic.

Species of Group IV:

- a) having ketopantoate hydroxymethyltransferase (*panB*)
- b) having pantothenate synthetase (*panC*)
- c) having aspartate-a-decarboxylase (*panD*)
- d) having ketopantoate reductase (*panE*)
- e) having acetohydroxyacid synthetase (*ilvBN*)
- f) having acetolactate synthase (*alsS*)
- g) having acetohydroxyacid isomeroreductase (*ilvC*)
- h) having dihydroxyacid dehydratase (*ilvD*)
- i) having a mutant valine-pyruvate amino acid transferase (*avtA*)
- j) having a mutant branched-chain amino acid transferase (*ilvE*)
- k) having a mutant asparaginase (*ansB*)

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- l) having a mutant acetolactate decarboxylase (*alsD*)
- m) having a *coaX* gene  
Claims 67-70, 72, 75, 88, 90, 108, 109
- n) having a *coaA* gene  
Claims 72, 73, 74, 75

For Group V, Claim 102 is generic.

Species of Group V:

- a) having ketopantoate hydroxymethyltransferase (*panB*)
- b) having pantothenate synthetase (*panC*)
- c) having aspartate-a-decarboxylase (*panD*)  
Claim 106
- d) having ketopantoate reductase (*panE*)  
Claim 104
- e) having acetohydroxyacid synthetase (*ilvBN*)
- f) having acetolactate synthase (*alsS*)
- g) having acetohydroxyacid isomeroreductase (*ilvC*)
- h) having dihydroxyacid dehydratase (*ilvD*)
- i) having a mutant valine-pyruvate amino acid transferase (*avtA*)
- j) having a mutant branched-chain amino acid transferase (*ilvE*)
- k) having a mutant asparaginase (*ansB*)
- l) having a mutant acetolactate decarboxylase (*alsD*)
- m) having a *coaX* gene  
Claims 110
- n) having a *coaA* gene

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added



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after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

### *Election*

5. A telephone call was made to Debra Milasineis on November 22, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

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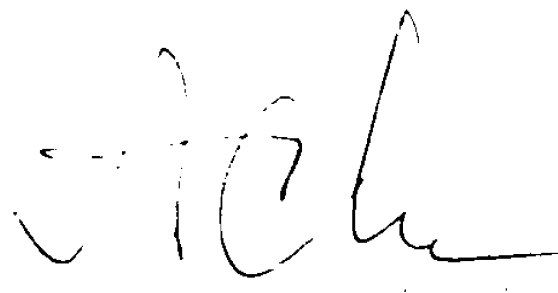
*Conclusion*

6. A complete response to the instant written restriction requirement must include an election of invention (Group) to be examined. Should Applicants' elect Groups I, II, IV, or V, the election must also include an election of species to be examined. This species will be examined first. If this species is allowable, the generic claims will be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
PONNATHUPURA  
ACHUTAMURTHY

KMK  
November 29, 2001